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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,287	06/21/2001	Andreas Sewing	MERCK-2261	2670

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EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 09/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/885,287	SEWING ET AL.
	Examiner	Art Unit
	Sharmila S. Gollamudi	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 05 June 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10 and 21-25 is/are pending in the application.

4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-10 and 21-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____

### **DETAILED ACTION**

Receipt of Amendment A received on June 5, 2003 is acknowledged. **Claims 1-10 and 21-25 are pending in this application.** Claims 11-20 have been withdrawn from prosecution in Paper No. 9.

#### ***Specification***

The amendment filed June 5, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant states that the specification has been amended because of obvious typographical error and refers to a US patent for support. However, support cannot be based on another patent and the instant application does not support such a change. The amendment of TiAl6V4 to Ti6Al4V is not supported since TiAl6V4 is a plausible compound (see page 11 of WO 92/13984) and it is the compound originally stated in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action unless support can be shown.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Rejection of claims 1-3 and 5-6 under 35 U.S.C. 102(b) as being anticipated by Sauk et al (4,780,450) is maintained.**

Sauk et al disclose a composition containing particulate calcium phosphate (hydroxyapatite) and type I collagen (col. 4, lines 59-66). A mixture of type I and type III collagen is taught (example 1).

\*Note that the recitation "for metallic implant materials" is intended use and is not given patentable weight.

***Response to Arguments***

Applicant argues that Sauk disclose composition containing polycrystalline phosphate ceramic, calcium salt, and collagen. It is argued that Sauk's composition is made via a different process. Applicant argues that the reference does not disclose a collagen matrix mineralized with calcium wherein the mineralized collagen are obtained by precipitating calcium phosphate from a solution in the presence of collagen.

Applicant's arguments have been fully considered but they are not persuasive. First, the examiner points out that the claim rejected are composition claims; therefore the process of coating does not hold patentable weight. Clearly from column 2, line 60 to column 3, line 5, Sauk discloses said composition, "the composition preferably comprise a mixture of phosphophoryn calcium, a matrix material (type I collagen), and calcium phosphate ceramic. These compositions are intended to facilitate matrix-mediated mineralization." Second, the instant claim language allows for the inclusion of other materials such as phosphophoryn calcium, in the composition. Lastly, the examiner points out that features which the applicant's arguments rely on, i.e. wherein

the mineralized collagen are obtained by precipitating calcium phosphate from a solution in the presence of collagen, is not recited in the claims.

**Claims 1-3 and 5-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Geistlich et al (5,573,771).**

Geistlich et al disclose a bone mineral product containing bone, collagen, and gelatin (examples and claims 1 and 8). The reference discloses that the natural bone used contains calcium phosphate, brushite, whitlockite, and octa-calcium phosphate (col. 1, lines 30-31). Type I or a mixture of type I-III is taught (col. 2, lines 41-43).

***Response to Arguments***

Applicant argues that Geistlich does not disclose a process for coating implants.

Applicant's arguments have been fully considered but they are not persuasive. The examiner points out that the rejected claims are composition claims and therefore the intended use of the composition, i.e. coating implants, does not hold patentable weight. The prior art clearly discloses a matrix containing collagen and calcium phosphate. See column 2, lines 23-53. As for claim 3, collagen in combination with mineral components inherently tends to separate phases or layers. See US Patent 5,543,441 column 3 lines, 66 to column 4, lines 5 as art of interest to support examiner's inherency argument.

**Rejection of claims 1-3, 5, and 7 under 35 U.S.C. 102(b) as being anticipated by Rhee et al (5,543,441) is maintained.**

Rhee et al teach implants coated with collagen-polymer conjugates. The composition contains collagen (Type I) and hydroxyapatite or gelatin beads (example 7).

***Response to Arguments***

Applicant argues that Rhee provides a collagen crosslinked to a polymer wherein calcium phosphate particles are dispersed. Applicant argues that the reference does not disclose a collagen matrix mineralized with calcium wherein the mineralized collagen are obtained by precipitating calcium phosphate from a solution in the presence of collagen.

First, the examiner points out that the claim rejected are composition claims; therefore the process of coating does not hold patentable weight. Second, the instant claim language allows for the inclusion of other materials such as polymers, in the composition. Lastly, the examiner points out that features which the applicant's arguments rely on, i.e. wherein the mineralized collagen are obtained by precipitating calcium phosphate from a solution in the presence of collagen, is not recited in the claims. Although, the examiner notes the difference in properties, the claims do not reflect this. The claims merely recite that the collagen is mineralized with calcium. Webster dictionary defines mineralizing as "to impregnate or supply with minerals." The definition of a matrix is "material in which something is enclosed or embedded." Therefore, since the hydroxyapatite or tricalcium phosphate is added to the collagen-polymer composition and is dispersed within, the prior art reads on the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Rejection of claim 8 under 35 U.S.C. 103(a) as being unpatentable over Geistlich et al (5,573,771) is maintained.**

Geistlich et al disclose a bone mineral product containing bone, collagen, and gelatin (examples and claims 1 and 8). The reference discloses that the natural bone used contains calcium phosphate, Brushite, whitlockite, and octa-calcium phosphate (col. 1, lines 30-31). Type I or a mixture of type I-III is taught (col. 2, lines 41-43). The reference teaches the inclusion of instant actives to destroy bacteria and aid in bone regeneration (col. 3, lines 20-60).

Geistlich et al do not exemplify the inclusion of the active agent.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include an active agent into the composition. One would be

motivated to do so since as taught by Geistlich, these actives can kill bacteria or encourage bone regeneration.

***Response to Arguments***

Applicant's arguments that the reference does not teach process for coating implants, has been addressed above.

**Claims are 1-5, 7-10, and 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rhee et al (5,543,441) in view of Shirkanzadeh (5,205,921) in further view of Kwan et al (5,776,193).**

Rhee et al teach implants coated with collagen-polymer conjugates. The composition contains collagen-polymer conjugates with hydroxyapatite for the repair of stress-bearing bone due to its high tensile strength (col. 6, lines 42-46). The composition may also include growth factors to encourage growth and heal wounds (col. 6, lines 46-62). The composition may be coated on a titanium implant by dipping (example 5). Rhee teaches that the amount of composition used will tend to depend on the severity of the condition to be treated, the amount of active agent incorporated into the composition, and the rate of delivery desired. Rhee teaches these parameters can be easily determined thorough routine experimentation. See column 12, lines 41-50.

Rhee et al does not specify the coating thickness on the implant and particle size.

Shirkanzadeh teaches a method of depositing bioactive coatings on conductive substrates. The substrate can be titanium or steel and the coating is 50 microns thick for a uniform, continuous, and firmly bonded coating. See example 4. The coating

composition includes hydroxyapatite in a particle range of 2-5 microns, instant doping agents, and collagen to produce the desired ceramic coating (col. 3, lines 5-20).

Kwan et al teach a mineralized collagen matrix containing calcium phosphate for bone grafting. Kwan teaches that the particles are of an average diameter of less than five microns since these particles are small enough to phagocytized to stimulated local reaction and further bone resorption. See column 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Rhee et al and Shirkanzadeh. One would be motivated to look to the guidance of Shirkanzadeh and coat the metal implant with instant thickness since the reference teaches that this thickness gives a uniform, continuous, and firmly bonded coating to the substrate. Further, one would expect similar results since Shirkanzadeh teaches the inclusion of collagen in the calcium phosphate coating composition and both references use the similar compositions and the same substrate. Lastly, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to manipulate the parameters of the coating thickness and particle size thorough routine experimentation as stated by Rhee et al. For instance one would be motivated to manipulate the particle size since Kwan teaches the utilization of particles with less than 5 microns to further bone resorption.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

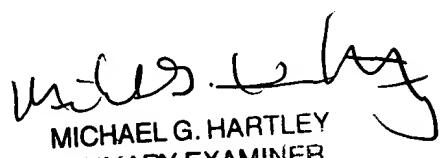
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG



  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER